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10/588,086	07/31/2006	Tadashi Yoneda	Q79826	4024

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EXAMINER	
HA, JULIE	
ART UNIT	PAPER NUMBER
1654	
MAIL DATE	DELIVERY MODE
04/29/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/588,086	YONEDA, TADASHI	
	Examiner	Art Unit	
	JULIE HA	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *1-10 and 19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/31/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Election/Restriction filed on March 20, 2008 is acknowledged. Claims 1-19 are pending in this application.

Restriction

1. Applicant's election without traverse of Group II (claims 11-18) and election of species wherein R is isoalkyl group having 11 carbon atoms, X is leucine, polyhydric alcohol is water and glycerin, tocopherol compound is δ-tocopherol and oil component is polyoxythylene (20) glyceryl triiostearate and glycerin tri-2-ethylhexanoate in the reply filed on March 20, 2008 is acknowledged. The restriction is considered proper and is made FINAL in this office action. Claims 1-10 and 19 are hereby withdrawn from further consideration, pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Claims 11-18 are examined on the merits in this office action.

Rejection

35 U.S.C. 112, 2nd

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 11-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claims 11-18 recite, "...the anionic surfactant having a lipopeptide structure..." The phrase "anionic surfactant having a lipopeptide structure" is unclear. It is unclear what is meant by lipopeptide structure, and if the anionic surfactant naturally has the structure of lipopeptide or is conjugated to the lipopeptide. Furthermore, it is unclear what a lipopeptide structure is. For example, claim 14 recites that "anionic surfactant having a lipopeptide structure is surfactin." It is unclear if anionic surfactant having a lipopeptide structure would always have the structure of surfactin. For example, ammonium lauryl sulfate is a well known anionic surfactant but has the structure

, and no peptide structure is conjugated to this anionic surfactant.

5. Claim 14 recites, "the method for improving...the anionic surfactant having a lipopeptide structure is surfactin represented by the following formula (1)...its homologue and/or salts thereof". This phrase is unclear. It is unclear what type of modifications would encompass the structural homologues of the anionic surfactant having a lipopeptide structure.

35 U.S.C. 112, 1st

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 11-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the

conclusion that the applicant was in possession of the claimed species is sufficient." MPEP 2163.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In Regents of the University of California v. Eli Lilly & Co., the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials. Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . ."). Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. The MPEP does state that for generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not define what constitute a sufficient number of representative, the Courts have indicated what do not constitute a representative number species to adequately describe a broad generic. In Gostelli, the Court determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872 F.2d at 1012, 10 USPQ2d at 1618.

In the instant case, the claims are drawn to a method for improving storage stability comprising addition of a tocopherol compound to an oil-based thickening gel composition comprising an anionic surfactant having a lipopeptide structure, a polyhydric alcohol having a valence of 3 or more, and an oil component. The claims are further drawn to anionic surfactant having a lipopeptide structure of formula (1)...its homologue and/or slats thereof. The generic statements an anionic surfactant having a lipopeptide structure and anionic surfactant having a lipopeptide structure of formula (1), its homologue and/or salts thereof does not provide ample written description for the compounds since the claims do not describe a single structural feature. The specification does not clearly define or provide examples of what qualify as compounds of the claimed invention.

As stated earlier, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable claims 11 and 14 are broad generics with respect all possible compounds encompassed by the claims. The possible structural variations are limitless to any class of peptide or a peptide-like molecule that form a peptidic bond with a lipid (or conjugated to a lipid), make up to class of anionic surfactants. It must not be forgotten that the MPEP states that if a peptide is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. Here, though the claims may recite some functional characteristics, the claims lack written

description because there is no disclosure of a correlation between function and structure of the compounds beyond compounds disclosed in the examples in the specification. Moreover, the specification lack sufficient variety of species to reflect this variance in the genus since the specification does not provide any examples of derivatives. The specification is void of organic molecules that functions as a peptide-like molecule that qualify for the functional characteristics claimed as a lipopeptide or a lipopeptide-like molecule or other peptidic molecules that can be linked to a lipid structure to become a lipopeptide, and other synthetic peptide or peptide-like molecule that can function as lipopeptides.

The specification is limited to the peptide or peptide-like molecules that belong to the same class of surfactant, the surfactin (see paragraph [0013]). The working example describes sodium surfactin as the anionic surfactin having a lipopeptide structure (see paragraph [0069]). The working example only describes the anionic surfactant lipopeptide surfactin being dissolved in glycerin (paragraph [0062]). The specification does not describe any anionic surfactant lipopeptide structure or any other homologs to the formula (1), such as any other type of peptide or peptide-like molecule, any small molecules that are peptide-like, amino acid mimetics or peptide-mimetics that can form peptide bonds and act as lipopeptide that are conjugated to anionic surfactants. Description of sodium surfactin (formula 1, having peptide sequence ELLVDL-X) for anionic surfactant having lipopeptide structure is not sufficient to encompass numerous other proteins that belong to the same genus. For example, there are varying lengths, varying amino acid compositions, and numerous distinct qualities that make up the

genus. There is not sufficient amount of examples provided to encompass the numerous characteristics of the whole genus claimed.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate"). Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Rejection-35 U.S.C. 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Kovacs et al (US Patent No. 5,583,105) as evidenced by Mishra et al (US Patent No. 6,284,268).

10. Kovacs et al teach an oral multiple emulsion preconcentrate comprising a surface active agent, ethanol, a lipophilic and/or amphiphilic solvent (see abstract). The

reference teaches that that the absorption of cyclosporin is improved...the ingredients do not precipitate during storage and the shelf-life of the composition is improved…decreasing the ratio of surfactant reduces high dispersivity grade of the emulsion. Vitamin E (tocopherol) decreases the neprhotoxic effect of cyclosporins (see Advantage, Derwent document 1996-240507 same as US Patent No. 5583105). Furthermore, the reference teaches that in some cases anionic surface active ingredients being present in significant quantity in the pharmaceutical preparation, make possible the absorption of the active ingredient under physiological conditions (see column 2, lines 21-28). Furthermore, the reference teaches that the fatty oils applied are known and the solvents were used as vehicles (see column 4, lines 36-38). The reference further teaches that the formulations are poured into 50 mls of water (see column 3, lines 29-30). As evidenced by Mishra et al, cyclosporin A is a poorly water soluble therapeutic agent (abstract). The instant claims are drawn to a method of stabilizing the storage conditions of a composition. Kovacs teaches the pharmaceutical composition comprising all the required elements as the instant claims. Thus, the reference disclose a method of stabilizing the composition. Therefore, since the composition comprises an anionic surfactant, a lipopeptide (cyclosporin), vitamin E (tocopherol) and lipophilic or amphiphilic solvent such as oil (see column 3, lines 9-10) in water, this composition would be stable and therefore, meets the limitation of claim 11.

Rejection-35 U.S.C. 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 11-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoneda et al (WO 03/013446 A1) in view of Goodman et al (U.S. Patent 4,883,659).

Yoneda et al teach an oily thickened gel-like which contains an anionic surfactant, water and/or polyhydric alcohol and oily ingredient; an emulsified composition obtained by adding water to the oily thickened gel-like composition; a cosmetic composition containing the oily thickened gel-like composition or the emulsified composition, and the anionic surfactant has a lipopeptide structure (see abstract). The reference further teaches that as a results of extensive investigations to attain the above-described object, the present inventors have found that an oily thickened gel-like composition comprising an anionic surfactant, water and/or polyhydric alcohol, and an oily ingredient can be prepared. In addition, when this oily thickened gel-like composition is diluted with water, a stable emulsified composition can be

obtained (see p. 4, lines 12-20). The reference further teaches the same surfactin compound formula (1) as the instant application. The reference teaches 0.01 to 45% anionic surfactant, water and/or polyhydric alcohol in an amount of 0.01 to 43%, oily ingredient in an amount of 1 to 99%...salt of surfactin and/or salt of the homologue of the sodium surfactin (see pp. 5-6), meeting the limitations of claims 13-16. The reference teaches that the liquid oil is one or more liquid oils such as glycerol tri(2-ethylhexanoate) (see p. 7, lines 10-13), one of the elected species of oil component. The reference further teaches that an antioxidant and a perfume can also be blended in the oily thickened gel-like composition…examples of the antioxidant which can be used include, tocopherol, tocopherol acetate, vitamin As such as retinoic acid, retinoic acid ester, retinol and retinoid (see pp. 16-17). The difference between the reference and the instant claims is that the reference does not teach the % anionic surfactant having a lipopeptide (0.01 to 5%), water and/or polyhydric alcohol (from 0.01 to 70%), oil component (30 to 99%), and tocopherol (0.01 to 2%).

Goodman et al teach that a skin treatment preparation (cosmetic as a film on the epidermal surface) that includes the addition of antioxidants and stabilizers, including tocopherol (or acetate) (see column 11, lines 20-25). The reference further teaches that the cosmetic formulations allow the inclusion of a variety of moisturizers/emollients other than the alcohols and surfactants above, such as anionic surfactants such as sodium lauryl sulfate (see column 10, line 51).

However, it would have been obvious to one of ordinary skill in the art to optimize the % concentrations of each component to arrive at an optimal composition. One of

ordinary skill in the art would have been motivated to optimize the % concentrations of each component, because the optimized composition would be most effective and would have the best storage conditions, and would have been motivated to add stabilizers such as tocopherol, since the Yoneda reference teaches that antioxidants may be added to the formulation. Furthermore, it is well known in the art that antioxidants, such as tocopherol are used as aid for stabilization of the beneficial agent against degradation such as oxidation (see Goodman et al). Therefore, it would have been obvious to one of ordinary skill in the art to add in the tocopherol (antioxidant) to stabilize the formulation. Furthermore, the MPEP states the following: Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. *"[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)* (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("*The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.*"); *In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA*

1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). There is a reasonable expectation of success, since the normal desire of scientists are to improve upon what is already generally known with routine optimization. Therefore, the instant claims are unpatentable over the cited prior arts.

Conclusion

14. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIE HA whose telephone number is (571)272-5982. The examiner can normally be reached on Mon-Thurs, 5:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Julie Ha/
Examiner, Art Unit 1654

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Primary Examiner, Art Unit 1654